2.   Remarks.

As amended, each independent claim is allowable. Comments specific to the independent claims follow:

Claim 1: Niemic describes activation of an alarm if a monitored condition (e.g., temperature, relative humidity, expiration date etc.) is above or below a predetermined threshold. The Examiner contends that Niemic's identification of an expiration date anticipates the claimed "potency condition." Without acquiescing to the Examiner's position, Niemic does not disclose or suggest apparatus in which the controller is capable of calculating a dosage in response to a calculated potency value.

Rocci et al. describe counting dosages delivered through an MDI, but not calculating a dosage in response to a calculated potency value.

Claim 14: amended to incorporate limitations from claim 15, which is noted by the Examiner to be allowable.

Claim 17: amended to incorporate limitations from claim 19 and is allowable for the reasons noted above with regard to claim 1.

Claim 22: amended to incorporate limitations similar to the limitation formerly in claim 20.

Claim 27: Niemic does not disclose or teach controller means configured for controlling the medication supply means in response to the calculated medication potency value.

These claims and all claims that depend from them are in condition for allowance.

Independent claims 32 and 33 are new and both are allowable.

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1.   **In th Claims.** The following listing of claims will replace all prior versions of the claims in the application:

1. (Currently Amended) Apparatus for determining potency of a medication, comprising:

a supply of medication in a container;

a temperature sensor operatively coupled to the container and capable of measuring the temperature of the medication to generate temperature data;

a programmable real time clock;

a controller programmed with medication temperature profile data specific to the medication, wherein the controller integrates temperature data and time data with medication temperature profile data on a continuous basis to generate a potency value for the medication and said controller calculates a medication dosage in response to the potency value.
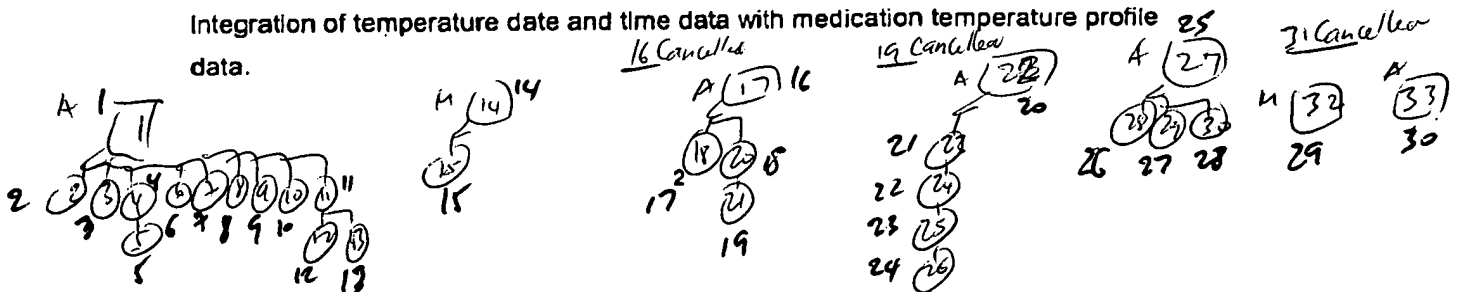
2. (Original) The apparatus of claim 1 wherein the controller accumulates temperature data and compares the temperature data to the medication temperature profile data according to a multiply and accumulate function to generate the potency value.

3. (Original) The apparatus of claim 1 including a programming interface operatively connected to the controller so that time data and medication temperature profile data may be programmed into the controller.

4. (Original) The apparatus of claim 1 including a display operatively connected to the controller for providing perceptible information corresponding to the potency value.

5. (Original) The apparatus of claim 4 wherein the container comprises a metered dose inhaler comprising a drop generator coupled to the supply of medication and the controller is configured for deactivating the drop generator in response to generation of a potency value that exceeds a predetermined threshold value.

6. (Original) The apparatus of claim 1 wherein the potency value corresponds to a predetermined potency condition of the medication based on integration of temperature date and time data with medication temperature profile data.

7. (Currently Amended) The apparatus of claim 1 wherein the ~~container~~ controller includes means for ~~decreasing~~ changing the dosage of medication in response to predetermined potency value of the medication based on integration of temperature date and time data with medication temperature profile data.

8. (Original) The apparatus of claim 1 wherein the temperature sensor comprises a temperature sensing integrated circuit in direct contact with the medication.

9. (Original) The apparatus of claim 1 wherein the temperature sensor comprises a temperature sensing integrated circuit in direct contact with the container.

10. (Original) The apparatus of clam 1 including a temperature sensor configured for measuring ambient temperature.

11. (Original) The apparatus of claim 1 wherein the container comprises a metered dose inhaler having a drop generator capable of expelling a dosage of medication through a mouthpiece.

12. (Original) The apparatus of claim 11 wherein the controller is programmed for adjusting the dosage of medication expelled through the mouthpiece in response to integration of temperature data and time data with medication temperature profile data.

13. (Original) The apparatus of claim 11 wherein the controller is programmed for disabling the drop generator in response to an expiration date.

14. (Currently Amended) A method of determining the potency of a medication in a medication delivery apparatus, comprising the steps of:

(a) monitoring the temperature of the medication over time;

(b) accumulating temperature data generated in step (a);

(c) comparing over time the accumulated temperature data with medication temperature profile data specific to the medication;

(d) calculating over time a potency condition of the medication based on the comparison of the accumulated temperature data with medication temperature profile data; and

(e) if the calculated potency condition equals a predetermined potency threshold, providing an alert of ~~an~~ medication expiration condition and disabling the medication delivery apparatus.

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15. (Original) The method of claim 14 including the step of delivering a dosage of medication det rmined by the comparison of the accumulated temperature data with medication temperature profile data.

16. (Canceled)

17. (Currently Amended) Apparatus for determining the therapeutic potency of a medication, comprising:

a temperature sensor operatively connected to a supply of a medication such that the temperature sensor measures the temperature of the medication to generate temperature data;

a real time clock circuit programmed with a begin date;

a controller programmed with medication temperature profile data specific to the medication and configured for accumulating temperature data and calculating an ongoing therapeutic potency condition based on comparison of the temperature data and medication temperature profile data;

means for delivering medication in a dosage determined by the therapeutic potency condition.

18. (Currently Amended) The apparatus of claim 17 including a user-readable display, and wherein when an expiration date is calculated an expiration alert message is displayed the user-readable display.

19. (Canceled)

20. (Currently Amended) The apparatus of claim 17 9 including means for ceasing delivery of medication when a predetermined potency threshold is met.

21. (Original) The apparatus of claim 20 wherein the supply of medication is contained in a metered dose inhaler.

22. (Currently Amended) A medication delivery apparatus, comprising:

a housing including a mouthpiece;

a supply of medication carried in a container in the housing;

a temperature sensor operatively coupled to the container and configured for measuring the temperature of the medication to generate temperature data;

a programmable real time clock;

a programmable controller with medication temperature profile data specific to the medication, wherein the controller is programmed to calculate on an ongoing basis a potency condition for the medication; said controller

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programmed to deactivate the apparatus in response to a calculated potency
value that exceeds a predetermined threshold value.

23. (Original) The medication delivery apparatus of claim 22 wherein the
controller integrates temperature data and time data with medication temperature
profile data to generate the potency condition.

24. (Original) The medication delivery apparatus of claim 23 wherein the
controller is programmed to calculate an expiration date for the medication when
integration of temperature data and time data with medication temperature profile
data generates a result that meets a predetermined threshold value.

25. (Original) The medication delivery apparatus of claim 24 including a
drop generator configured for generating droplets of medication and expelling the
droplets through the mouthpiece in response to activation of a switch.

26. (Original) The medication delivery apparatus of claim 25 wherein the
controller is programmed to deactivate the switch in response to calculation of an
expiration date.

27. (Currently Amended) A pharmaceutical container, comprising:

medication supply means for containing a pharmaceutical;

temperature sensor means for measuring the temperature of the
pharmaceutical and for thereby generating temperature data;

real time clock means;

medication delivery means for delivering a controlled dosage of the
medication to a patient;

controller means with medication temperature profile data specific to the
medication, the controller means configured for calculating a medication potency
condition based on integration of temperature data and medication temperature
profile data over time; said controller means configured for deactivating the
medication delivery means to prevent delivery of medication if the calculated
medication potency condition meets a predetermined threshold.

28. (Original) The apparatus of claim 27 wherein the temperature sensor
means further comprises a temperature sensing integrated circuit.

29. (Original) The apparatus of claim 27 wherein the real time clock means
further comprises a programmable real time clock integrated circuit.

30. (Original) The apparatus of claim 27 including medication delivery
means for delivering a controlled dosage of the medication to a patient and

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wherein the controller means further comprises means for controlling the dosage of delivered medication based upon the calculat d pot ncy condition.

31. (Canceled)

Please add the following new claims:

32. (New) A method of determining the potency of a medication In a medication delivery apparatus configured for delivering a dosage of medication to a patient, comprising the steps of:

(a) monitoring the temperature of the medication over time;

(b) accumulating temperature data generated in step (a);

(c) comparing over time the accumulated temperature data with medication temperature profile data specific to the medication;

(d) calculating over time a potency condition of the medication based on the comparison of the accumulated temperature data with medication temperature profile data; and

(e) adjusting the dosage of medication delivered to the patient in response to the calculated potency condition.

33. (New) Apparatus for determining the therapeutic potency of a medication, comprising:

a temperature sensor operatively connected to a supply of a medication such that the temperature sensor measures the temperature of the medication to generate temperature data;

a real time clock circuit programmed with a begin date;

a controller programmed with medication temperature profile data specific to the medication and configured for accumulating temperature data and calculating an ongoing therapeutic potency value based on comparison of the temperature data and medication temperature profile data; and

means for changing the dosage of medication delivered to a patient In response to the therapeutic potency value.

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